April 5, 2005

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510(k) Submission

Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed/Linvatec is hereby submitting a 510(k) Summary of Safety and Effectiveness for the LightWave™ Integrated Electrode Ablator and LightWave™ Integrated Electrode Suction Ablator

510(k) # K050923

A. Submitter

ConMed/Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Elizabeth Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: LightWave™ Integrated Electrode Ablator and
LightWave™ Integrated Electrode Suction Ablator

Common Name: Electrode

Classification Names: Electrosurgical cutting and coagulation device and accessories, CFR 878.4400

Proposed Class/Device: Class II
Product Code: JOS & GEI

Summary of Safety and Effectiveness
LightWave™ Integrated Electrode Ablator and
LightWave™ Integrated Electrode Suction Ablator
510(k) # K050923
April 5, 2005

D. Predicate/Legally Marketed Devices

K993885 - UltrAblator, Linvatec Corporation

K002422 - VAPR™ 3.5mm 90° Suction Electrode for use with the VAPR™ System, Mitek Products

K021299 - Heatwave Hand-Controlled Electrode, ConMed Corporation

K030720 - UltrAblator, Linvatec Corporation

K983652 - Linvatec Switch Pencil, Linvatec Corporation

E. Device Description

The ConMed/Linvatec LightWave™ Integrated Electrode Ablators are a modification of the currently marketed 3.2 mm UltrAblator electrode (Linvatec, K030720) and a Switch Pencil control handle (Linvatec, K983652) integrated into one device. One version incorporates hand-controlled buttons to actuate the "cut" and "coag" functions of the electrosurgical generator. Another version is actuated by foot-control to control "cut" and "coag" functions of the electrosurgical generator. The hand-controlled and foot controlled version consists of an electrical insulation coated electrode and ceramic insulator attached to an integrated handle and cord set, allowing attachment to commonly available electrosurgical generators in distribution.

A third version of the ConMed/Linvatec LightWave™ Integrated Electrode Ablators incorporates a suction/aspiration feature and is a modification of the currently marketed 3.2 mm UltrAblator electrode (Linvatec, K993885) and a Switch Pencil control handle (Linvatec, K983652) integrated into one device, and is similar in technology to Heatwave Hand-Controlled Electrode (Conmed, K021299) and the VAPR™ 3.5mm 90° Suction Electrode (Mitek, K002422), which incorporate aspiration or suction. The device is similar to the hand-controlled device and will also have suction capability and attach to commonly available suction equipment. This electrode will be hollow allowing for the removal of irrigating fluids during surgical procedures.

The front switch contained in the hand-controlled devices provide the surgeon with electrosurgical cut (ablate) capability when depressed. The rear button activates electrosurgical coagulating (coag) current.

F. Intended Use

The ConMed/Linvatec LightWave™ Integrated Electrode Ablators are intended to be used for electrosurgical cutting and coagulation in shoulder, ankle, wrist, elbow, and knee arthroscopic procedures in a conductive fluid environment. Additionally, the suction/aspiration version also has capability for suctioning irrigation fluids.

G. Substantial Equivalence

The ConMed/Linvatec LightWave™ Integrated Electrode Ablators are substantially equivalent to the identified predicate devices below in intended use and surgical effect, function, materials of construction, patient population, compliance with recognized standards and published FDA guidance for devices of this type, and manufacturing methods. The predicate devices are intended for use in conjunction with an electrosurgical generator controlled by hand or footswitch for use during arthroscopic procedures. Either hand control or foot switch control are used to control the duration of electrosurgical current delivered to the operative site via the electrode. The ConMed/Linvatec LightWave™ Integrated Electrode Ablators are a one-piece design that incorporates the functions of the Linvatec brand predicate devices, as well as similar performance and technological characteristics of the other predicate devices, into one ergonomic handle and electrode combination. Differences exist between the predicates and new device in that one version of the new device offers a suction feature through the electrode center with maximum cut power of 200 watts. A comparison table of the currently marketed devices and the device subject to this application submission is attached.

Substantially Equivalent Predicate Marketed Devices:

K993885 - UltrAblator, Linvatec Corporation
K002422 - VAPR™ 3.5mm 90° Suction Electrode for use with the VAPR™ System, Mitek Products
K021299 - Heatwave Hand-Controlled Electrode, Conmed Corporation
K030720 - UltrAblator, Linvatec Corporation
K983652 - Linvatec Switch Pencil, Linvatec Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2005

Ms. Elizabeth M. Paul
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K050923
Trade/Device Name: LightWave™ Integrated Electrode Ablator and
LightWave™ Integrated Electrode Suction Ablator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: JOS & GEI
Dated: April 11, 2005
Received: April 13, 2005

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050923

Device Name:
LightWave™ Integrated Electrode Ablator and
LightWave™ Integrated Electrode Suction Ablator

Indications for Use:

The ConMed/Linvatec LightWave™ Integrated Electrode Ablators are intended to be used for electrosurgical cutting and coagulation in shoulder, ankle, wrist, elbow, and knee arthroscopic procedures in a conductive fluid environment. Additionally, the suction/aspiration version also has capability for suctioning irrigation fluids.

Prescription Use_X_ OR Over-the-Counter Use_____
(Part 21 CFR 801 subpart D) (Part 21 CFR 807 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...(Sign-Off)
...Restorative
...Devices
K050923